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Prospective assessment of ultrasonography findings in the diagnosis of ectopic pregnancy

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Abstract:

Background: Ectopic pregnancy is a potentially life-threatening condition requiring prompt diagnosis. Ultrasonography plays a central role in early detection, but its diagnostic accuracy varies across clinical settings. Aim: To evaluate the diagnostic accuracy of ultrasonography in detecting ectopic pregnancy among women with suspected ectopic pregnancy.

Methods: This prospective diagnostic accuracy study was conducted from February to May 2025 at a tertiary care hospital. Women of reproductive age presenting with clinical suspicion of ectopic pregnancy were enrolled. All participants underwent transabdominal and transvaginal ultrasound examination. Ultrasound findings were compared with operative findings and/or definitive clinical follow-up, which served as the reference standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall accuracy, and ROC curve analysis were performed.

Results: Out of 60 participants, ectopic pregnancy was confirmed in 70.0% of cases. Ultrasonography demonstrated high sensitivity and PPV with good overall diagnostic accuracy. The ROC curve showed excellent discriminatory ability, supporting ultrasound as an effective diagnostic tool.

Conclusion: Ultrasonography is a dependable first-line investigation for suspected ectopic pregnancy, though negative findings require careful follow-up to avoid missed diagnoses.

Keywords: Ectopic pregnancy, Transvaginal ultrasound, Diagnostic accuracy, ROC curve, Early pregnancy complications

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Introduction:

Ectopic pregnancy is a major cause of acute morbidity in early gestation, and delayed recognition may lead to tubal rupture, life-threatening hemorrhage, and loss of fertility [1]. Modern care therefore emphasizes rapid, reliable diagnosis using a triad of clinical evaluation, serial serum β-hCG, and pelvic ultrasonography, with transvaginal ultrasound (TVUS) offering superior resolution for early uterine and adnexal assessment [1]. Recent clinical data comparing TVUS with transabdominal ultrasound demonstrate higher diagnostic performance and lower misdiagnosis rates with TVUS, reinforcing its role as the preferred first-line imaging modality in suspected ectopic pregnancy [2]. Indian hospital-based observations further highlight that ultrasound findings such as hemoperitoneum and adnexal mass, when interpreted alongside symptoms and signs, support timely case identification and appropriate triage [3]. Emerging techniques such as contrast-enhanced ultrasound may further improve lesion conspicuity and diagnostic accuracy in tubal ectopic pregnancy, but require evaluation in routine settings [4]. Against this background, local estimates of diagnostic accuracy is essential for protocol optimization, training, and audit in emergency gynecology units at our tertiary care hospital. The of the study is to determine the diagnostic accuracy of primarily TVUS for detecting ectopic pregnancy among women presenting with suspected ectopic pregnancy, using operative findings and/or definitive clinical follow-up as the reference standard.

Methods:

This prospective diagnostic accuracy study was conducted at Aster CMR Hospital from February to May 2025, after obtaining the required approvals. Consecutive women of reproductive age presenting to the emergency department or obstetrics and gynecology outpatient services with clinical suspicion of ectopic pregnancy were screened for eligibility. Suspicion was based on symptoms such as amenorrhea, lower abdominal pain, vaginal bleeding, syncope, or shock, along with a positive urine pregnancy test or elevated serum β-human chorionic gonadotropin (β-hCG). Women who provided written informed consent were enrolled.

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Patients with confirmed intrauterine pregnancy on initial ultrasound, those with heterotopic pregnancy, and women who declined consent were excluded. Baseline demographic details, obstetric history, clinical presentation, vital parameters, and laboratory findings including serum β-hCG levels were recorded using a predesigned structured proforma.

All enrolled participants underwent ultrasonographic evaluation as part of the initial diagnostic work-up. Transabdominal ultrasound was performed first using a low-frequency curvilinear probe, followed by TVUS using a high-frequency endovaginal probe for detailed pelvic assessment. Ultrasound examinations were conducted by radiologists with experience in gynecologic imaging, who were blinded to the final surgical or follow-up outcomes at the time of scanning. Sonographic parameters assessed included presence or absence of an intrauterine gestational sac, adnexal mass, tubal ring sign, free fluid in the pelvis or abdomen, and evidence of hemoperitoneum. Based on these findings, the ultrasound diagnosis was categorized as ectopic pregnancy, intrauterine pregnancy, pregnancy of unknown location, or non-pregnancy-related pathology. The ultrasound impression was documented immediately after the examination.

The reference standard for diagnosis was defined as intraoperative findings in patients who underwent surgical management (laparoscopy or laparotomy) and/or definitive clinical follow-up in conservatively managed cases. Surgical findings confirming tubal or extra-tubal ectopic pregnancy were considered diagnostic. In patients managed expectantly or medically, diagnosis was confirmed by serial β-hCG trends and repeat ultrasound findings demonstrating resolution or progression consistent with ectopic pregnancy or intrauterine pregnancy. Ultrasound results were compared with the reference standard to determine diagnostic performance. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy of ultrasonography were calculated. Data were entered into Microsoft Excel and analyzed using SPSS version 21. Categorical variables were expressed as frequencies and percentages, and continuous variables as mean with standard deviation. Diagnostic accuracy indices were reported with 95% confidence intervals, and a p value <0.05 was considered statistically significant.

Results:

A total of 60 women with suspected ectopic pregnancy were evaluated during the study period. The mean age of participants was 27.8 ± 4.6 years, with the majority presenting with amenorrhea (93.3%) and lower abdominal pain (81.7%). Ultrasonographic assessment revealed an empty uterus in nearly three-fourths of cases, while adnexal masses and free pelvic fluid were observed in 60.0% and 46.7% of women, respectively. Based on operative findings and clinical follow-up, ectopic pregnancy was confirmed in 42 patients (70.0%). When ultrasound findings were compared with the reference standard, true positive (TP) diagnoses were made in 38 cases, while 4 cases of ectopic pregnancy were missed on initial ultrasound examination. There were 3 false-positive (FP) diagnoses and 15 true-negative (TN) cases. Ultrasonography demonstrated a sensitivity of 90.5% and specificity of 83.3% in detecting ectopic pregnancy. The PPV was high at 92.7%, indicating that most ultrasound-positive cases were true ectopic pregnancies. The NPV was 78.9%, reflecting a small proportion of missed diagnoses. The overall diagnostic accuracy of ultrasound was 88.3%, which was statistically significant ($p < 0.05$). These findings indicate that ultrasonography, particularly transvaginal ultrasound, is a reliable and effective first-line imaging modality for the diagnosis of ectopic pregnancy in a tertiary care emergency setting.

Discussion:

In Table 1, the baseline profile shows that most women with suspected ectopic pregnancy were in the late 20s, with a predominance of multigravida and a symptom pattern led by amenorrhea and lower abdominal pain, followed by vaginal bleeding, which is consistent with the fact that the “classic triad” is common but not universal and many women present with overlapping, variable symptoms rather than a single textbook picture [5]. The high frequency of amenorrhea and pain in your cohort mirrors prospective Indian hospital data where reproductive-age women (often 20–30 years) formed the largest group and amenorrhea and abdominal pain were the most frequent presenting complaints, reinforcing that these baseline clinical cues remain highly useful for early suspicion in emergency settings [6]. Table 1 also indicates clinically relevant antecedents such as prior abortion and previous pelvic surgery, which are important because such factors can be associated with tubal pathology and subsequent ectopic implantation, and recent large observational profiles from Indian tertiary centers similarly highlight that women may present with few or no classic risk factors, yet histories suggesting pelvic/tubal compromise (e.g., pelvic inflammatory disease, prior procedures/surgery, prior pregnancy terminations) can be contributory in a meaningful proportion [7]. Overall, the baseline distribution in Table 1 supports the real-world pattern of ectopic pregnancy: a disease of reproductive-age women with nonspecific but recurring symptom clusters and heterogeneous risk backgrounds, underlining why a structured triage approach that combines symptoms, vitals, pregnancy testing and urgent ultrasound is

essential for timely diagnosis and prevention of rupture-related morbidity [5].

In Table 2, the predominance of an empty uterus underscores a key early-pregnancy imaging scenario: in suspected ectopic pregnancy, absence of an intrauterine gestational sac (especially when β-hCG is at/above the discriminatory zone) heightens suspicion but remains non-specific and must be interpreted alongside adnexal evaluation and clinical stability [5]. The high frequency of adnexal mass in your series is clinically important because adnexal abnormalities represent the most consistent ultrasound correlate of tubal ectopic implantation, often appearing as an inhomogeneous/complex mass or a discrete extrauterine gestational structure, and modern diagnostic pathways place major emphasis on meticulous adnexal scanning by TVUS [8]. Notably, the tubal ring sign observed in a substantial subset strengthens diagnostic confidence because a ring-like echogenic structure in the adnexa is a relatively specific sign of tubal ectopic pregnancy and is often used to support definitive labeling when a live extrauterine embryo is not seen [5]. The presence of free pelvic fluid and particularly hemoperitoneum in Table 2 has direct triage value, as these findings can indicate active bleeding or rupture risk and therefore help prioritize urgent surgical evaluation or escalation of care in symptomatic patients [8]. From a workflow perspective, Table 2 also supports a practical point: combining modalities can improve feature detection (e.g., adnexal mass, pelvic effusion, pseudo-sac), especially when abdominal windows are suboptimal or early lesions are small, and recent evidence shows that vaginal ultrasound and combined (vaginal + abdominal) approaches can enhance visualization of key sonographic signs and reduce missed diagnoses in suspected ectopic pregnancy populations [9]. Finally, emerging methods such as contrast-enhanced ultrasound (CEUS) are being studied to further improve diagnostic certainty in atypical cases, suggesting a future direction for imaging escalation when standard TVUS is equivocal despite persistent clinical suspicion [10].

In Table 3, ectopic pregnancy constituted 70.0% of women evaluated for suspected ectopic pregnancy, while 23.3% were ultimately confirmed to have an intrauterine pregnancy and 6.7% remained classified as pregnancy of unknown location (PUL). This distribution is clinically plausible because study enrolment was based on *suspected* ectopic pregnancy in an emergency/tertiary-care pathway, where pre-test probability is high and triage prioritizes symptomatic women or those with inconclusive early findings [5]. At the same time, the presence of a substantial intrauterine pregnancy proportion highlights a key real-world challenge—early pregnancy symptoms (pain/bleeding) overlap considerably across viable intrauterine pregnancy, miscarriage, and ectopic pregnancy, making imaging and follow-up essential to avoid both missed ectopic pregnancy and inappropriate interruption of a desired intrauterine pregnancy [5]. The small but important PUL category in Table 3 reflects the well-recognized interim diagnosis when a pregnancy test is positive but ultrasound cannot yet localize the gestation; modern reviews emphasize that PUL requires structured follow-up using serial β-hCG (± progesterone) and repeat ultrasound to safely differentiate resolving pregnancies, early intrauterine pregnancies, and occult ectopic pregnancies [11]. Importantly, prospective hospital-based studies from India report comparable clinical pathways where a significant fraction of symptomatic early pregnancies are ultimately ectopic, reinforcing the need for standardized algorithms integrating ultrasound and biochemical monitoring, especially in high-volume tertiary settings [6].

In Table 4, ultrasonography correctly identified most confirmed ectopic pregnancies (high true positives) with only a small number of missed cases (false negatives), indicating strong performance of ultrasound as the first-line test in symptomatic early pregnancy evaluation [12]. The presence of a few FPs is clinically expected because adnexal complex masses, hemorrhagic corpus luteum, and early pregnancies of unknown location can mimic ectopic pregnancy on a single scan, which is why most guidelines emphasize integrating ultrasound with serial β-hCG trends and short-interval follow-up when findings are equivocal [13]. Importantly, the missed ectopic pregnancies (FNs) in Table 4 may reflect very early gestation (small tubal lesions), suboptimal visualization, or classification as "pregnancy of unknown location" at the initial encounter; in such scenarios, expert recommendations stress repeat transvaginal scanning and careful adnexal assessment rather than relying only on the absence of an intrauterine sac [2].

Table 5 demonstrates that ultrasound achieved high sensitivity and high PPV, meaning that a positive ultrasound impression was highly reliable for true ectopic pregnancy in your setting, which is consistent with evidence showing that transvaginal sonography can accurately diagnose a large proportion of ectopic pregnancies before surgery when diagnosis is based on positive adnexal visualization rather than "empty uterus" alone [2]. The specificity and NPV, while still good, were comparatively lower than sensitivity and PPV, suggesting that a negative scan did not completely exclude ectopic pregnancy and supports the need for structured follow-up protocols, particularly in clinically suspicious cases or when β-hCG is rising without localization [13]. Overall, the combined interpretation of Tables 4 and 5 indicates that ultrasound is an effective front-door diagnostic tool

for ectopic pregnancy triage, but optimal safety is achieved when ultrasound findings are embedded within an algorithm that includes clinical risk assessment, hemodynamic status, β-hCG monitoring, and repeat imaging for indeterminate cases [12].

Conclusion: This prospective study demonstrates that ultrasonography, particularly transvaginal ultrasound, is a reliable and effective first-line imaging modality for the diagnosis of ectopic pregnancy in a tertiary care setting. The high sensitivity and positive predictive value observed indicate strong diagnostic confidence when ultrasound findings are positive. However, the comparatively lower negative predictive value highlights that a negative scan does not completely exclude ectopic pregnancy, emphasizing the importance of clinical correlation and serial β-hCG monitoring. Overall, integrating ultrasound with biochemical and clinical assessment enables timely diagnosis, appropriate triage, and reduction of ectopic pregnancy–related morbidity and mortality.

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Table 1: Baseline demographic and clinical characteristics (n = 60)

Variable	Number
Mean age*	27.8 ± 4.6
Gravidity ≥2	38 (63.3%)
Amenorrhea	56 (93.3%)
Lower abdominal pain	49 (81.7%)
Vaginal bleeding	34 (56.7%)
History of prior abortion	18 (30.0%)
Previous pelvic surgery	12 (20.0%)
*Mean ± SD in years	

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Table 2: Ultrasound findings among study participants	
Ultrasound finding	**Number**
Empty uterus	44 (73.3%)
Adnexal mass	36 (60.0%)
Tubal ring sign	22 (36.7%)
Free fluid in pelvis	28 (46.7%)
Hemoperitoneum	14 (23.3%)

Table 3: Final diagnosis based on reference standard	
Pregnancy diagnosis	**Number**
Ectopic	42 (70.0%)
Intrauterine	14 (23.3%)
Unknown location	4 (6.7%)
Total	60 (100%)

Table 4: Comparison of ultrasound diagnosis with reference standard		
Ultrasound diagnosis	**Ectopic**	
	Present	**Absent**
Positive	38 (TP)	3 (FP)
Negative	4 [False Negative (FN)]	15 (TN)

Table 5: Diagnostic accuracy parameters of ultrasound	
Parameter	**Value (%)**
Sensitivity	90.5
Specificity	83.3
PPV	92.7
NPV	78.9
Overall accuracy	88.3